

**REMARKS**

Claims 1 - 11 and 25 were previously canceled. Thus, claims 12-24 remain pending in the present application. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are in condition for allowance.

Claims 12 - 24 stand rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,766,174 to Perry in view of U.S. Patent No. 5,041,115 to Frigg et al. (hereinafter "Frigg") in further view of U.S. Patent No. 6,547,791 to Buhren et al. (hereinafter "Buhren") in further view of U.S. Patent No. 6,270,499 to Leu et al. (hereinafter "Leu"). (See 7/13/11 Office Action, p. 2).

Claim 12 recites, in relevant part, an intramedullary nail "wherein the isthmus locking section includes a proximal through hole and a distal through hole, the proximal through hole being arranged at an angle of 90° relative to the distal through hole." The Examiner again acknowledges that Perry, Frigg, and Buhren do not disclose an isthmus locking section including two through holes arranged at a relative angle A as recited. (See 7/13/11 Office Action, p. 5). The Examiner again attempts to cure this deficiency with Leu.

It was previously submitted that the Examiner's assertion that the bores 7 and the anteroposterior bore 29 being disposed on a portion of the intramedullary nail 1 of Leu analogous to the recited isthmus locking section is misplaced. The Examiner responds to this argument by stating that arguments against the references individually cannot show non-obviousness. That is, the Examiner is modifying the medial holes of Perry with the features of Leu. (See 7/13/11 Office Action, p. 7). However, it is respectfully submitted that the disclosure of Leu was being introduced to indicate that one skilled in the art would not have a reasonable expectation of success from the purported modification. Among other criteria, an obviousness argument requires that there be a reasonable expectation of success. (See MPEP 2143.02). The previously

submitted arguments clearly show that the bores 7, 29 of Leu relate to a different area of the bone (that is not the isthmus). An isthmus locking section of an intramedullary nail is a portion of the nail which, when implanted to a desired location, is located within the isthmus of the bone - i.e., the thin shaft extending between the enlarged ends of the bone. Those skilled in the art understand that fractures in this area require different treatment than those on the trochanteric area and that portions of a nail extending within the isthmus will be subjected to different forces and, therefore, have specific structural requirements that distinguish isthmian portions of nails from the ends which reside outside the isthmus. In its entirety, Leu neither states nor suggests that the bores 7, 29 are located at the isthmus of the bone. In contrast, as illustrated in Fig. 1 and the annotated Fig. 1 provided by the Examiner, the bores 7, 29 are within the thickened trochanter at the proximal end of the bone – outside of the isthmus. Specifically, Leu states that the bores 7 are “in the area of the proximal end 3” of the nail. (See Leu, col. 3, line 57). As the bore 29 is between the bores 7, it is also in the area of the proximal end 3. Furthermore, Leu states that a “preferred refinement” of the invention consists of a bore running across the central axis of the nail “in the area of the proximal end” to lock the nail in position. (Id., col. 2, lines 63 - 67). Therefore, it is respectfully maintained that one skilled in the art would not have a reasonable expectation of success for the purported modification in view of the disclosure of Leu.

It was further respectfully submitted that the intramedullary nail 1 of Leu is described as functioning as an intramedullary angle plate providing increased contact between the implant and bone to permit reconstruction of the head of the tibia even if that tibia is osteoporitic. (See Id., col. 2, ll. 40 - 53). Specifically, the head 10 of the nail at the proximal end is required to lock the nail in position even where bone quality is low. Thus, the bores 7 and 29 are provided not in the isthmus, but in the thickened end of the bone to increase bony purchase as the head 10 of the nail 1 provides the load-bearing element. (See Id., col. 2, ll. 54 - 67). In addition, Leu shows the nail 1 including bores 6 and a threaded bore 8 at the *distal end* of the nail 1 to be disposed near the isthmus of the bone, not for a *medial* locking section. (See Id., Figs. 1, 4, 6). As described in the specification, these bores are located “in the area of the distal end” of the nail. (Id. at col. 2, lines

63 - 67). Thus, it is respectfully maintained that Leu does not disclose or suggest an isthmus locking section and, accordingly, through holes thereof. Furthermore, it is again respectfully submitted that one skilled in the art would not have a reasonable expectation of success for this purported modification in view of these further details of Leu.

Furthermore, it was previously submitted that Leu fails to disclose or suggest the angular relationship of claim 12 stated *arguendo* if the bores 7, 29 were considered through holes of an isthmus locking section (which is not conceded). Specifically, Leu only teaches bores 7 and an anteroposterior bore 29 extending through the intramedullary nail 1 that are arranged in a non-parallel fashion, but includes absolutely no showing or suggestion that any of these bores is perpendicular to any other. (See Leu, col. 3, ll. 57-62; Figs. 1, 4, 6). In its entirety, Leu includes no disclosure with respect to the angles of these bores relative to one another. In response to this argument, the Examiner states that it should have been obvious to achieve the recited angular relationship by trial and error. However, it is respectfully submitted that the Examiner's assertion is unsupported by the disclosure of Leu which does not indicate the specific 90° orientation and that the Examiner's assertion is based instead on impermissible hindsight. It is respectfully maintained that no conclusion about the angular relationship between the bores may properly be drawn from an examination of the drawings alone or the obviousness basis provided by the Examiner and that Leu does not cure the deficiencies of Perry, Frigg and Buhren.

In addition, the previously presented arguments related to the misplaced assertion that the device of Perry even being modifiable is respectfully maintained. Specifically, the device of Perry including the various components do not enable any of the purported modifications asserted by the Examiner. In response to this argument, the Examiner states that a location would be known if the angular relationship is known. However, it is respectfully submitted that the Examiner may have disregarded several requirements necessary prior to determining of the location. Specifically, the device of Perry is explicitly configured with parallel transfixation holes 32a, 32b, 34a, 34b so that insertion of a locating screw 28 into an indent 59 formed in anvil

assembly 26 aligns the guides holes 40a, 40b, 42a, 42b of the alignment tower 24 with respective transfixation holes 32a, 32b, 34a, 34b of the intramedullary nail 20. (See Leu, col. 3, ll. 33-40; col. 5, l. 40 - col. 6, l. 2; Figs. 1-3). Perry teaches only one possible configuration of the alignment tower 24 with respect to the intramedullary nail 20 (*i.e.*, the configuration assumed when the locating screw 28 is received in the indent 59). Accordingly, the transfixation holes 34a and 34b of Perry which purportedly correspond to the through holes of the isthmus locking section of claim 12 can be disposed only in the disclosed parallel configuration. It is unclear how any of the cited references would be adapted for Perry with regard to the 90° orientation when a primary focus in Perry is to provide a definitive means for locating the transfixation holes through the proper alignment thereof for the introduction of transfixation screws specifically with the described components therein. Thus, it is respectfully maintained that Perry is incapable of being modified to overcome this limitation.

It is therefore respectfully submitted that Perry, Frigg, Buhren, and Leu, taken alone or in combination, do not disclose or suggest “wherein the isthmus locking section includes a proximal through hole and a distal through hole, the proximal through hole being arranged at an angle of 90° relative to the distal through hole,” as recited in claim 12 and that claim 12 is in condition for allowance. Because claims 13 - 22 depend from and include the limitations of claim 12, it is respectfully submitted that these claims are also allowable.

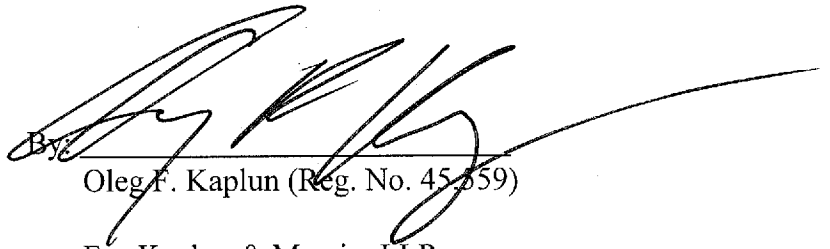
Claim 23 recites limitations substantially similar to claim 12, including an intramedullary nail “wherein the isthmus locking section includes a proximal through hole and a distal through hole, the proximal through hole being arranged at an angle of 90° relative to the distal through hole.” It is therefore respectfully submitted that claim 23 is also allowable over Perry, Frigg, Buhren, and Leu, taken alone or in combination, for substantially the same reasons noted above with respect to claim 12. Because claim 24 depends from and includes the limitations of claim 23, it is respectfully submitted that this claim is also allowable.

In light of the foregoing, Applicants respectfully submit that all of the pending claims are in condition for allowance. All issues raised by the Examiner having been addressed, and an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

Dated:

9/9/11



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